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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,487	09/27/2004	Vijaya Juturu	NUTR1.025NP	5408

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
STONE, CHRISTOPHER R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
02/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,487	JUTURU ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *9-11 and 14-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed November 7, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-50 are pending. Claims 9-11 and 14-50 are withdrawn. Claims 1-8, 12 and 13 are currently under examination. Contraceptive drugs and non-steroidal anti-inflammatory drugs (NSAIDs) are the species of insulin resistance inducing drug currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz (US 2002/0086065) in view of Godsland et al (Journal of Endocrinology and Metabolism, 74(1), p. 64-70, 1992).

Claims 1-7, 12 and 13 are drawn to a method of inhibiting the development of drug induced insulin resistance comprising administering chromium picolinate contemporaneously with oral contraceptive drugs or NSAIDs.

Katz teaches a method of decreasing insulin resistance comprising the oral administration of chromium picolinate at a daily dose of 1000 micrograms of chromium in a pharmaceutically acceptable carrier (paragraphs 0049, 0050 and 0071). Katz does not teach the step of identifying an individual receiving a dose of a drug (e.g. oral contraceptives) that induces insulin resistance and then administering chromium picolinate contemporaneously with said drug.

Godsland et al teaches that oral contraceptive drugs cause insulin resistance (p. 69, left column, 1st full paragraph).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to identify an individual receiving a dose of a drug that induces insulin resistance (i.e. oral contraceptives) and to then administer chromium picolinate contemporaneously (e.g. simultaneously or within a 24 hour period) with said drug to alleviate/reduce a known side effect of the drug, since oral contraceptives were known to cause insulin resistance and chromium picolinate was

known to treat insulin resistance and would have been expected to treat/aleviate the oral contraceptive induced insulin resistance when coadministered, simultaneously or within a 24 hour period, with said contraceptive drug, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katz (US 2002/0086065) and Godsland et al (Journal of Endocrinology and Metabolism, 74(1), p. 64-70, 1992) as applied above, further in view of Goodman and Gilman's, The Pharmacological Basis of Therapeutics, Eight Edition, 1995.

Katz (US 2002/0086065) and Godsland et al (Journal of Endocrinology and Metabolism teach the aforementioned method but do not explicitly teach the parental administration of the chromium picolinate.

Goodman and Gilman's teaches that parenteral administration is a common route of administration without many disadvantages of oral administration including: the incapability to absorb some drugs because of their physical characteristics, emesis as a result of irritation to the gastrointestinal mucosa and destruction of some drugs by digestive enzymes or low gastric pH (p. 5, right column through p. 6).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to administer the composition of Katz parenterally to overcome the many disadvantages of oral administration, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Applicant argues that neither Katz or Goodman's and Gilman's teach or suggest the step of identifying a subject receiving a dose of a drug that induces insulin resistance. This is found unpersuasive because newly applied Godsland et al suggests the step of identifying a subject receiving a dose of a drug that induces insulin resistance rendering obvious the instantly claimed invention for the reasons noted above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is

(571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

27January2009
CRS

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645